### REMARKS

Entry of the foregoing amendments is respectfully requested.

## **Summary of Amendments**

Upon entry of the foregoing amendments, claims 24-47 are cancelled and claims 48-71 are added, whereby claims 48-71 will be pending, with claims 48 and 69 being independent claims.

Support for the new claims can be found throughout the present specification and in the original claims.

Applicants emphasize that the cancellation of claims 24-47 is without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute the cancelled claims in one or more continuation and/or divisional applications.

# **Summary of Office Action**

As an initial matter, Applicants note with appreciation that the Examiner has indicated consideration of the Information Disclosure Statement filed December 31, 2006. In this regard it is noted that Applicants have in the meantime (on September 17, 2009) filed a Supplemental Information Disclosure Statement; accordingly, the Examiner is respectfully requested to indicate consideration of the Supplemental Information Disclosure Statement by returning a signed and initialed copy of the Form PTO-1449 submitted therein with the next communication from the Patent and Trademark Office.

Applicants further note with appreciation that the Examiner has acknowledged the claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f) and the receipt of a certified copy of the priority document.

The restriction requirement is made final and claims 29-47 are withdrawn from consideration.

Claim 27 is objected to.

Claims 24-28 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

Claim 28 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

Claims 24-26 and 28 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lilley et al., GB 2 359 746 (hereafter "LILLEY").

Claims 24-28 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LILLEY in view of Vail III et al., US 2004/0009245 (hereafter "VAIL").

# Response to Office Action

Reconsideration and withdrawal of the objection and rejections of record are respectfully requested, in view of the foregoing amendments and the following remarks.

### Response to Objection to Claim 27

Claim 27 is objected to. In particular, the Examiner requests that the acronym "MRSA" recited therein should be spelled out.

In response, Applicants have spelled out the acronym "MRSA" in claims 60 and 70 submitted herewith.

### Response to Rejection under 35 U.S.C. § 112. First Paragraph (Enablement)

Claims 24-28 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The rejection asserts that the specification, while being enabling for a method of treating microbe-caused disease of at least one condition disclosed in the instant claims, allegedly does not reasonably provide enablement for preventing a microbe-caused disease.

Applicants respectfully traverse this rejection. In particular, at the bottom of page 6 of the instant specification the meaning of the term "prophylaxis" is set forth in detail. Further, at pages 10 to 16 of the instant specification many specific examples of prophylactic treatments by using oil of coriander are disclosed.

Particular attention is directed to the fact that in the instant specification "prophylaxis" or "prophylactic treatment" is always mentioned together with the "treatment" of the same diseases, thereby providing the teaching that with respect to the steps to be performed there is no difference between the "treatment" of a disease (i.e., in a case where the patient/subject suffers from the disease) and the "prophylaxis" or prevention of the disease (i.e., in a case of prophylaxis as defined

at the bottom of page 6 of the specification: (i) preventive treatment of a healthy user or "patient" in order to prevent said user from catching a disease, or (ii) preventive treatment of a still healthy user, but one who has a certain susceptibility to a microbial disease; or (iii) preventive treatment of a still healthy user, but one having a certain pre-disposition for the disease; or (iv) preventive treatment of a user who has had the disease already but has overcome such a disease, e.g., by a successful treatment). In all of these prevention scenarios the same "treatment" steps have to be performed as in the case of the treatment of an actual disease. This is possible due to the fact that oil of coriander is not a drug (in the usual sense) but a natural substance which may be used in a way similar to other natural substances (e.g., other essential oils).

At any rate, it is apparent to one of ordinary skill in the art that in a case where a certain substance (e.g., oil of coriander) is suitable for treating a microbe-caused disease of skin, a mucous membrane and/or the oral cavity, the substance must be capable of killing (or at least inhibiting) the corresponding microbes. If the substance is capable of killing/inhibiting the microbes it is equally apparent that the substance will not only kill/inhibit the microbes which have already caused a disease (= treatment) but will also kill/inhibit the (same) microbes which are capable of causing the disease but have not yet done so (= prevention). In view thereof, it is evident that the same steps which will result in the treatment of a microbe-caused disease in an already afflicted patient will prevent the disease in a subject which has not yet developed the disease.

Applicants submit that for at least all of the foregoing reasons, the rejection under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the enablement requirement is without merit and should be withdrawn, which action is respectfully requested.

### Response to Rejection under 35 U.S.C. § 112. First Paragraph (Written Description)

Claim 28 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The rejection alleges that with respect to the recitation of "a derivative thereof and a metabolite thereof" the written description is not commensurate in scope with the claims.

Applicants respectfully disagree with the Examiner in this regard as well. At any rate, claim 28 is cancelled and the claims submitted herewith do not recite a derivative or metabolite, whereby this rejection is moot.

# Response to Rejection under 35 U.S.C. § 103(a) over LILLEY

Claims 24-26 and 28 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LILLEY. The rejection alleges, *inter alia*, that LILLEY "beneficially teaches the instant claims by disclosing one or more essential oils selected from coriander and others therein for the inhibition of pathogenic bacteria in the oral cavity that define such disorders as gingivitis, periodontal disease, dental carries and particularly disorders related to or caused by the activity of anaerobic bacteria (gram positive bacteria)". The rejection concedes that LILLEY does not teach the step of administering coriander oil to a mammal but alleges that it would have been obvious to one of ordinary skill in the art to administer coriander oil to a mammal based on the beneficial teachings provided by LILLEY.

Applicants respectfully traverse this rejection as well. Specifically, it is pointed out that LILLEY is directed to the antimicrobial effects of (inter alia) oil of coriander-containing

compositions for inhibiting anaerobic bacteria in the oral cavity in cases of treatment of dental caries, gingivitis and/or periodontal disease by oral administration. No suggestion can be found in LILLEY relating to any treatment of the skin or any mucosa (mucous membranes) with respect to microbecaused diseases. On the contrary, at page 3, lines 14-23 thereof LILLEY states (emphasis added):

It has now been found that certain essential oils, which in earlier studies had previously demonstrated only weak antibacterial activity, are particularly potent in their antibacterial effect against species of bacteria which are strongly implicated in periodontal disease and/or malodour production.

According to the present invention there is provided the use of an effective amount of one or more essential oils selected from coriander oil, cumin oil, dill weed oil, lemongrass oil and peppermint oil in the manufacture of a composition for the inhibition of pathogenic bacteria, particularly anaerobic bacteria, present in the oral cavity of humans and other mammals, the composition being suitable for oral administration.

The above passage conveys the strong impression that the oils disclosed in LILLEY exhibit significant activity only against "species of bacteria which are strongly implicated in periodontal disease and/or malodour production", which is a <u>disincentive</u> rather than a motivation for one of ordinary skill in the art to use a substance such as oil of coriander for the treatment or prevention of a disease which is not "strongly implicated in periodontal disease and/or malodour production".

It further is noted that it appears that according to LILLEY the preferred oil is cumin oil (see, e.g., claim 11 of LILLEY), i.e., not coriander oil.

Applicants submit that for at least all of the foregoing reasons, LILLEY is unable to render obvious the subject matter of any of the claims submitted herewith, wherefore withdrawal of the rejection under 35 U.S.C. § 103(a) over LILLEY is warranted and respectfully requested.

## Response to Rejection under 35 U.S.C. § 103(a) over LILLEY in View of VAIL

Claims 24-28 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LILLEY in view of VAIL. The Examiner concedes that LILLEY fails to teach that coriander oil treats multi-resistant pathogens but alleges that VAIL "beneficially discloses that concentrated oil vapors from essential oils of coriandrum and other essential oils therein can be used to treat MRSA" wherefore it would allegedly have been obvious to one of ordinary skill in the art to combine the teachings of LILLEY and VAIL.

This rejection is respectfully traversed as well. Applicants submit that the teachings of LILLEY and VAIL are completely unrelated, wherefore it is only with <u>hindsight</u> that one can conclude that one of ordinary skill in the art would be motivated to combine these teachings.

In particular, LILLEY explicitly teaches the treatment of diseases selected from dental caries, gingivitis and/or periodontal disease by oral administration of compositions of, *inter alia*, oil of coriander in the oral cavity (see the introduction on page 2, page 3, third to fifth paragraphs, page 4, second paragraph, experimental part, and claims 1, 3 and 6).

In contrast, VAIL discloses the inhalation of <u>concentrated vapors</u> of essential oils for preventing, treating and curing infections by respiratory pathogens causing SARS  $\geq$  30 min before entering public areas (see, e.g., claim 1 of VAIL). Further, according to the abstract of VAIL "[c]oncentrated vapors from botanical essential oils are inhaled to prevent, treat and cure infections of the respiratory pathogens causing Severe Acute Respiratory Syndrome ("SARS"). These vapors are inhaled as a practical method to reduce the risks of infection by the pathogens causing SARS in crowded public places. These vapors are also inhaled as a practical method to reduce the risks of

infection by unknown, and unpredictable, respiratory pathogens that may be present in public places. The essential oils have antiseptic properties, are safe to inhale, and include, but are not limited to, the essential oils from Eucalyptus globulus, Melaleuca alternifolia, Eucalyptus citriodora, and Eucalyptus radiata."

Accordingly, apart from the fact that both documents mention oil of coriander, LILLEY and VAIL have nothing in common. For example, while LILLEY discloses the use of oil of coriander in the <u>oral cavity</u>, VAIL teaches the inhalation of <u>concentrated vapors</u> of the essential oil into the <u>lungs</u> (see, for example, paragraph [0355] of VAIL), the interior of which is "wetted" by these vapors.

It further must not be overlooked that oil of coriander is mentioned in VAIL, i.e., a document having more than 60 pages, only <u>once</u>, i.e., as one of a total of almost <u>130</u> examples of essential oils which are suitable for the purposes set forth in VAIL (see pages 15 and 16 thereof). Moreover, oil of coriander is not included in the list of preferred essential oils set forth in, e.g., claim 17 of VAIL (and neither is any of the other essential oils mentioned in LILLEY).

In addition, MRSA appears to be mentioned in the disclosure of VAIL also only <u>once</u>, i.e., as one of a total of more than <u>260</u> examples of pathogens which according to VAIL can be combated with concentrated vapors of essential oils (see pages 19 to 22). MRSA also is not included in the list of pathogens set forth in, e.g., claims 11 to 16 of VAIL. Further, despite the large number of exemplary pathogens set forth in VAIL, these pathogens do not appear to include <u>any</u> of the pathogens which are mentioned in the Examples of LILLEY.

Applicants submit that for at least all of the foregoing reasons, VAIL fails to teach or suggest that concentrated vapors of oil of coriander (let alone oil of coriander as such) are able to treat

diseases which are caused by MRSA and thereby also fails to cure the noted deficiencies of LILLEY,

even if one were to assume, arguendo, that one of ordinary skill in the art would be motivated to

combine the teachings of LILLEY and VAIL. In view thereof, it is apparent that the instant rejection

under 35 U.S.C. § 103(a) over these documents is without merit as well, wherefore withdrawal

thereof is respectfully requested.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in

condition for allowance, which action is respectfully requested. If any issues yet remain which can

be resolved by a telephone conference, the Examiner is respectfully invited to contact the

undersigned at the telephone number below.

Respectfully submitted, Matthias AUGUSTIN et al.

/Heribert F. Muensterer/

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